HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

New Format of HPRA Safety Notices

Priority 3 – Advisory

HPRA Safety Notice: SN2014(16)

Issue Date: 01 April 2014
Revised: 06 November 2015

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
N/A	N/A

ISSUE
Based on feedback received from our stakeholder communications questionnaire and discussions with various interested bodies, the HPRA has revised the format of medical device safety notices.

ACTION OR RECOMMENDATIONS
Medical device users are encouraged to familiarise themselves with the new safety notice format. Where appropriate, the HPRA will endeavour to include a picture to assist users in identifying the affected medical devices and understanding the issue.

TARGET GROUPS	
All medical device users.	

BACKGROUND

A key part of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of the incident or to alleviate the consequences of such incidents. The aim of HPRA safety notices is to advise the user of the device, whether that is at home, in a hospital or in a community setting, of important information regarding the safe use of their medical device.

The HPRA circulates safety notices in many instances. Some examples are included below:

- To highlight a serious public health issue.
- To draw attention to field safety corrective actions which, following a HPRA risk assessment, are deemed to be related to medium or high risk safety issues.
- To highlight an issue that has already been communicated by a manufacturer via a field safety notice but where the manufacturer has indicated to the HPRA that they have experienced difficulty reaching all customers or obtaining feedback from all customers.
- To highlight an issue when either the device manufacturer or distributor to the Irish market no longer exists. For example, where the manufacturer has gone into liquidation or where the manufacturer is not known e.g. counterfeit devices.
- To communicate concerning trends identified by the HPRA in relation to particular product families.
- To communicate safety concerns identified by the HPRA in monitoring vigilance issues e.g. equipment management issues and traceability issues.

Due to the varying nature of these safety notices, the HPRA intends to prioritise these communications. A traffic light system of red, amber and green will be used to aid in dissemination of safety information. The proposed system is risk based and is outlined below:

Priority	Category	Examples
Priority 1	**For Immediate Action**	• Urgent product removal • Urgent information
Priority 2	**Warning**	• Action required • Caution in use
Priority 3	**Advisory**	• Traceability issue • Generic information regarding medical devices

All safety notices will be assigned a priority number (1-3) and will be categorised as outlined in the above table. The examples included in the third column of the above table are not an exhaustive list.

The new format will also provide information on the target audience, the background to the issue and details of the recommended actions.

In practice, HPRA safety notices are only issued for a small percentage of the overall FSNs distributed in Ireland. The recipient of the safety communication should ensure that the communication reaches the most appropriate personnel within their organisation. The recipient should also ensure that the issue outlined in the notice is considered, the risks assessed and the appropriate / recommended actions are completed.

In some instances, the recipient of the notice may not be the most appropriate person to deal with the issue, therefore a well defined, effective mechanism for managing the communications is necessary. Some organisations, hospitals and the community care setting have found that it is very beneficial to have one designated medical device vigilance contact, a local medical device vigilance team that meet to assess the issues that arise, local medical device vigilance procedures and a database to support the management of such communications. Such structures and defined responsibilities and processes help to ensure that the communications are dealt with in a timely manner.

Another key element of the vigilance system is user reporting. The HPRA currently operates a voluntary system whereby a user, healthcare professional or any other person who identifies a medical device safety issue can report it to the HPRA. The HPRA strongly encourages healthcare professionals and members of the public who have encountered a safety issue with a medical device that they have used to report this to the HPRA.

Safety notices will be published on the HPRA website (www.hpra.ie) and will continue to be circulated, at the time of publication, to healthcare professionals who have subscribed to the HPRA mailing list. The HPRA will also circulate, via email, a listing of HPRA safety notices at the end of each calendar month.

The HPRA will no longer circulate MHRA medical device alerts (MDAs). Medical device users can continue to receive MDAs by registering with the MHRA website.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie